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INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P044137	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/JP 03/04649	International filing date (day/month/year) 11.04.2003	Priority date (day/month/year) 12.04.2002
International Patent Classification (IPC) or both national classification and IPC A23C19/032		
Applicant MEIJI DAIRIES CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☐ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  12.09.2003	Date of completion of this report  13.07.2004
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Baminger, U  Telephone No. +49 89 2399-2176  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/JP 03/04649**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-3, 5-32 as originally filed  
4 received on 21.04.2004 with letter of 19.04.2004

**Claims, Numbers**

1-10 received on 21.04.2004 with letter of 19.04.2004

**Drawings, Sheets**

5/9-9/9 as originally filed  
1/9-4/9 received on 30.12.2003

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
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International application No. **PCT/JP 03/04649**

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

**see separate sheet**

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-10
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-10
Industrial applicability (IA)	Yes: Claims	1-10
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**Re Item I**

**Basis of the opinion**

The amendments to p. 25 and 22 filed with letters of 30.12.03 and 19.4.04 respectively go beyond the disclosure of the international application as filed (Art. 34(2)(b)). It is not clear on which basis these contradicting amendments/corrections to tables 4 and 7 are performed. Therefore these amendments are not allowed.

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: WO 01 88150 A (GERMOND JACQUES EDOUARD ;MOLLET BEAT (CH); NESTLE SA (CH)) 22 November 2001 (2001-11-22) cited in the application
- D2: EP-A-1 112 692 (MEIJI MILK PRODUCTS COMPANY LT ;WAKAMOTO PHARMA CO LTD (JP)) 4 July 2001 (2001-07-04) cited in the application & JP 2001 000143 A 9 January 2001 (2001-01-09)
- D3: PATENT ABSTRACTS OF JAPAN vol. 2000, no. 16, 8 May 2001 (2001-05-08) & JP 2001 002578 A (KOGA YASUHIRO;MEIJI MILK PROD CO LTD; WAKAMOTO PHARMACEUT CO LTD), 9 January 2001 (2001-01-09)
- D4: US 2002/037341 A1 (LEE JEONG JUN ET AL) 28 March 2002 (2002-03-28)
- D5: WO9827825

5.1 The subject-matter of claim 1 is novel (Art. 33 (2) PCT) in view of the documents available to the examiner.

The same applies mutatis mutandis to the independent claims 5 and 6.

5.2 For the purpose of examining the inventive step of claim 1, D2 can be regarded as

the closest prior art.

D2 (cf. ex. 1 and 2 and claims) discloses a food or drink product such as a fermented milk or yoghurt with a disinfecting property against *Helicobacter pylori* comprising *Lb. gasseri* OLL 2716.

D2 therefore differs with the present application in that a cheese comprising *Lb. gasseri* is not disclosed.

The problem to be solved by the present application therefore lies in the provision of an alternative milk product comprising *Lb. gasseri* with a disinfecting potency against *Helicobacter pylori*.

The solution over D2 found in claim 1 of the present application is the preparation of a cheese instead of a yoghurt or acid milk. D1 (claims 2 and 9) discloses a cheese comprising *Lactobacillus gasseri*, without giving an indication that this organism has a disinfection potency against *Helicobacter pylori*. D1 (cf. p. 5, lines 24-28 and claims) and D4 (claims 1 and 4) give clear indications that it is possible to prepare a cheese comprising very closely related lactobacilli of the acidophilus group (*Lb. johnsonii* in D1 and *Lb. acidophilus* in D4) with such an effect (displacing *Helicobacter* in D1 and inhibiting growth of *Helicobacter* in D4). Therefore claim 1 can not be considered inventive according to Art. 33 (3) PCT.

The same applies *mutatis mutandis* to the independent claim 5.

As for independent claim 6, D5 (cf. claims 1, 3, 4) discloses a process for production of a cheese wherein yeast extract is added to pasteurised milk before fermentation with *Lb. johnsonii*, as a result of which a curd is formed.

- 5.3 A positive preliminary examination report for the dependent claims can not be established since the requirements of the PCT concerning inventive step for the independent claims are not complied with.

## CLAIMS

1. Natural cheese which comprises a lactic acid bacterium belonging to *Lactobacillus gasseri* having a disinfection potency against *Helicobacter pylori*.
2. The natural cheese according to claim 1, wherein the lactic acid bacterium is resistant to low pH environment.
3. The natural cheese according to claim 1 or 2, wherein the lactic acid bacterium is *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) or a mutant thereof.
4. The natural cheese according to any of claims 1 to 3, wherein the lactic acid bacterium is present at a viable count of  $10^7$  cfu/g or more when preserved at a temperature of  $10^{\circ}\text{C}$  or less for 6 months.
5. ~~A food which comprises the natural cheese according to any one of claims 1 to 4.~~
6. (Amended) A process for producing the natural cheese according to any one of claims 1 to 4, which comprises:

adding an yeast extract to a milk component before formation of a curd.

7. The process according to claim 6, wherein the curd is incubated without being cooled after molding and pressing.

8. The process according to claim 6 or 7, wherein the curd is incubated at 20 to 35°C for 16 to 26 hours.

9. The process according to any one of claims 6 to 8, wherein a lactic acid bacterium belonging to *Lactobacillus gasseri* having a disinfection potency against *Helicobacter pylori* is added to raw milk as a starter.

10. The process according to any one of claims 6 to 9, wherein the lactic acid bacterium is *Lactobacillus gasseri* OLL 271-6 (FERM BP-6999) or a mutant thereof.

The present invention relates to the following (1) to (8):

(1) Natural cheese which comprises a lactic acid bacterium belonging to *Lactobacillus gasseri* having a disinfection potency against *Helicobacter pylori*.

(2) The natural cheese according to (1), wherein the lactic acid bacterium is resistant to low pH environment.

(3) The natural cheese according to (1) or (2), wherein the lactic acid bacterium is *Lactobacillus gasseri* OLL 2716 (FERM BP-6999) or a mutant thereof.

(4) The natural cheese according to any of (1) to (3), wherein the lactic acid bacterium is present at a viable count of  $10^7$  cfu/g or more when preserved at a temperature of  $10^{\circ}\text{C}$  or less for 6 months.

(5) A food which comprises the natural cheese according to any one of (1) to (4).

(6) A process for producing the natural cheese according to any one of (1) to (4), which comprises:

~~adding a yeast extract to a milk component before formation of a curd.~~

(7) The process according to (6), wherein the curd is incubated without being cooled after molding and pressing.



problem was noticeable concerning the flavor of the gouda cheese (Table 6).

Table 4  
Changes in bacterial count during the process of producing  
*L. gasseri* OLL 2716-containing gouda cheese

Step	<i>L. gasseri</i> count (log cfu/g)	Other bacteria (log cfu/g)
Sterilized milk	-	3.48
<i>L. gasseri</i> starter	9.03	-
CHN-01 starter	-	9.03
Raw milk with starter	6.79	6.92
Whey	6.08	6.04
Salt-free curd (Day produced)	8.74	9.23
Salt-containing curd (Day following production)	8.75	9.69

Table 5  
Changes in bacterial count during preservation of  
*L. gasseri* OLL 2716-containing gouda cheese

Preservation temperature	Preserved at 10°C (log cfu/g)				Preserved at 5°C (log cfu/g)			
	Center		Surface		Center		Surface	
Preservation time	LG	Others	LG	Others	LG	Others	LG	Others
Immediately after production	8.75	9.69	8.74	9.67	-	-	-	-
After 1 week	8.78	9.74	8.60	9.66	-	-	-	-
After 2 weeks	8.81	9.77	8.38	8.76	-	-	-	-
After 1 month	8.60	9.04	7.78	8.73	8.78	9.62	7.78	8.73
After 2 months	8.00	8.60	7.10	8.42	8.60	9.20	7.48	8.70
After 3 months	8.08	7.41	-	-	8.38	8.75	-	-
After 4 months	7.60	7.04	-	-	8.04	8.86	-	-
After 5 months	7.38	7.36	-	-	8.04	7.79	-	-
After 6 months	7.67	6.20	<6.00	<6.00	8.01	7.30	<6.00	<6.00

LG: *L. Gasseri*

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